

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NOVO NORDISK A/S and
NOVO NORDISK, INC.,

Plaintiffs,

Case No. 05-40188

-vs-

CARACO PHARMACEUTICAL
LABORATORIES, LTD. and
SUN PHARMACEUTICAL INDUSTRIES, LTD.,

HON. AVERN COHN

Defendants.

MEMORANDUM AND ORDER DENYING WITHOUT PREJUDICE DEFENDANTS'
RENEWED MOTION FOR SUMMARY JUDGMENT ON SIXTH AFFIRMATIVE
DEFENSE OF PATENT MISUSE (Doc. 500)¹

This is a patent casein involving the diabetes drug repaglinide marketed by plaintiffs Novo Nordisk A/S and Novo Nordisk, Inc. (Novo) under the trade name Prandin. Novo's patent for repaglinide, U.S. Pat. No. RE37,035 (the '035 patent), expired on March 14, 2009. Novo also holds a patent on the combination of repaglinide and metformin, U.S. Pat. No. 6,677,358B1 (the '358 patent) which does not expire until 2018. This case began in 2005 when Novo sued Caraco Pharmaceutical Laboratories, Ltd (Caraco) and Sun Pharmaceutical Industries, Inc. (Sun) claiming infringement of the '358 patent when Caraco applied to the FDA to market a generic version of repaglinide. Caraco and Sun countersued for declaratory relief, raising issues including validity, enforceability, and misuse.

¹The Court deems this matter appropriate for decision without oral argument.
See Fed. R. Civ. P. 78(b); E.D. Mich. LR 7.1(f)(2).

After over five years of litigation, one appeal, and a three-week bench trial on the issues of patent validity and enforceability, the Court issued a decision finding the patent invalid on the grounds of obviousness and unenforceable due to Novo's inequitable conduct before the patent office.² Novo v. Caraco, 2011 WL 163996 (E.D. Mich. Jan. 19 2011). January 19, 2011. Doc. 532. Novo has appealed this decision. Doc. 525.

Following the bench trial, Caraco filed the instant renewed motion for summary judgment on patent misuse. The motion relates to Novo's listing of the '358 patent in the FDA's Orange Book. Caraco contends that the manner in which Novo changed the "use code" of the '358 patent from "Use of repaglinide in combination with metformin to lower blood glucose" to "A method for improving glycemic control in adults with type 2 diabetes mellitus, pre" violates the letter and purpose of FDA regulations and was done with the intent to mislead the FDA as to the scope of the '358 patent. As such, Caraco says Novo has engaged in patent misuse.

The parties have filed detailed motion papers. After carefully reviewing the papers, and considering the circumstances of this case, the motion must be denied without prejudice. The factual basis for the patent misuse – Novo's conduct before the FDA regarding the Orange Book – is the same factual basis for Caraco's counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii), in which Caraco requested an order requiring Novo to change the use code for the '358 patent. The Court granted Caraco's motion on the

²During the pendency of the bench trial, Novo moved to dismiss the case for lack of subject matter jurisdiction. The Court denied the motion. Doc. 507.

counterclaim, finding that Novo had improperly filed an overbroad use code narrative for the '358 patent and granted injunctive relief. See Docs. 421, 423. The Court of Appeals for the Federal Circuit held, 2-1, that the statute did not provide an avenue for relief and reversed. Novo v. Caraco, 601 F.3d 1359 (Fed. Cir. 2010). Novo has filed a petition for certiorari from that decision, which is pending. See 79 U.S.L.W. 3403 (Dec 23, 2010)(NO. 10-844, 10A380).

Although the Court expressly declined to address the issue of patent misuse in dealing with Caraco's counterclaim, and the Federal Circuit acknowledged as much, due to the pendency of Novo's appeal from the bench decision and Caraco's petition for certiorari coupled with the notion that there appear to be factual disputes with respect to Novo's actions before the FDA, it would be inappropriate for the Court to consider Caraco's motion regarding patent misuse at this time. Accordingly, the motion is DENIED WITHOUT PREJUDICE.

SO ORDERED.

S/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: February 24, 2011

I hereby certify that a copy of the foregoing document was mailed to the attorneys of record on this date, February 24, 2011, by electronic and/or ordinary mail.

S/Julie Owens
Case Manager, (313) 234-5160